



9342 '99 DEC 22 A9 52

December 13, 1999

The Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: 21 CFR Parts 210, 211, 820, and 1271**  
***Suitability Determination for Donors of Cellular & Tissue-Based Products***

To Whom It May Concern:

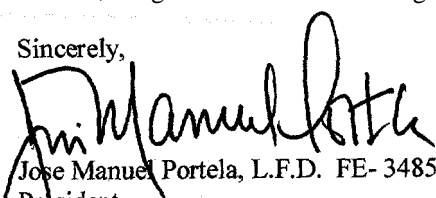
As a Licensed Funeral Director of the State of Florida, I am writing to express my opposition to the proposed Food and Drug Administration's rule to require a donor medical history interview for all **corneal** donors. I am proud of the fact that the Florida Lions Eye Bank has, over the past 38 years, provided more than 32,000 corneas to patients totally **free** of charge. This has saved the Medicare program more than \$ 1,000,000 each year **from** the Florida Lions Eye Bank alone.

The FDA's effort to address transmissions of Creutzfeldt Jakob Disease (**CJD**) will eliminate the most successful eye bank program in the nation. While the motive is admirable, the new requirement will not serve **that** purpose. The medical advisor to the **Florida** Lions Eye Bank state that the **additional** next of kin screening requirements will not add to the safety of corneal tissue for CJD. This has been well demonstrated 32,000 times over the past 38 years.

As you must know, patients who have symptoms for CJD usually die in hospitals and are of advanced age (over 60). The Florida Lions Eye Bank's Medical Examiner's program obtains corneas **from** those who die a sudden accidental death. Their ages typically range from 20-40 years of age. This is not a high-risk group. Also, those who die a sudden death from other causes, but who might have the disease in the latent stage, would not exhibit any symptoms of **CJD**... thus asking even hundreds of questions regarding behavior, etc. would serve no purpose.

Each day in South Florida many new patients are added to the waiting list for **corneal** transplantation. Unnecessary screening will further delay the wait time and extend the suffering and impaired vision of many men, women and children. In addition, if the eye bank is force to hire more employees to try to track down someone to interview on each suitable case at the medial examiner's offices, it **will** become necessary to begin to charge a processing fee. Since the majority of **corneal** recipients are over 65, the government will be charge for a service provided free for 38 years.

Sincerely,

  
Jose Manuel Portela, L.F.D. FE- 3485  
President  
Soc. Sec. # 583-81-6636

Cc: US. Senators Bob Graham, Connie **Mack**  
U.S. Representatives Charles T. Canady, Dan Miller, Porter J. Goss, Dave **Weldon**,  
Mark Foley, Carrie Meek, Ileana Ros-Lehtinen, Robert Wexler, Peter Deutsch, Lincoln **Diaz-Balart**,  
E. Clay Shaw, Jr., Alcee Hastings



*Funeraria  
Broward*

*Funeral Home*

5980 W. Oakland Park Blvd.  
Lauderhill, Florida 33313



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